

Medical Marijuana Advocates for Research

Petitioner

V.

**Rachel L. Levine, MD, Secretary,
Pennsylvania Department of Health,**

Respondent.

No. MD 2018

**ORDER GRANTING
APPLICATION FOR SPECIAL RELIEF
IN THE NATURE OF A PRELIMINARY INJUNCTION**

NOW, this ____ day of _____, 2018, Petitioner's application
for special relief in the nature of a preliminary injunction is hereby granted.

1. Respondent Rachel L. Levine, MD, Secretary, Pennsylvania Department of Health, is hereby preliminarily enjoined from enforcing the regulations affecting Clinical Registrants at 28 Pa. Code §§ 1211.27, 1211.28, 1211.30, 1211.31, 1211.32, and 1211.34 promulgated August 18, 2018 at 48 Pa. B. 5027 (Revised Chapter 20 Regulations), pending the outcome of this litigation or further order of court.

2. Petitioner shall post bond in the amount of \$100.

3. Should Respondent appeal this order, such appeal shall not act as a supersedeas under Pa. R.A.P. 1736(b). The applicable standards for vacating a Rule 1736(b) supersedeas are substantially identical to those for granting a preliminary injunction. *See Department of Environmental Resources v. Jubelirer*, 614 A.2d 199 (Pa. 1989). Accordingly, the Court's grant of a preliminary injunction demonstrates that Petitioner would be entitled to have any Rule 1736(b) supersedeas vacated. Under the circumstances of this case, and in the interests of judicial economy, the Court makes that ruling at this time.

BY THE COURT:

J.

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Medical Marijuana Advocates for
Research

Petitioner,

v.

Rachel L. Levine, MD, Secretary,
Pennsylvania Department of Health,

Respondent.

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No. MD 2018

**APPLICATION FOR SPECIAL RELIEF
IN THE NATURE OF A PRELIMINARY INJUNCTION**

Petitioner Medical Marijuana Advocates for Research (MMAR) respectfully applies, pursuant to Pa. R.A.P. 1532(a), for a Preliminary Injunction to prevent enforcement of the Department of Health's (DOH) August 18, 2018 temporary regulations at 28 Pa. Code §§ 1211.21- 1211.37, 48 Pa.B. 5027, (Revised Chapter 20 Regulations) purporting to implement the Clinical Registrant provisions contained in recently-amended Chapter 20 (Chapter 20) of the Medical Marijuana Act, 35 P.S §§ 10231.2001-2003 (Act or Medical Marijuana Act), *as amended*, P.L. 322, No. 43, June 22, 2018 (Act 43).¹

¹ DOH's Revised Chapter 20 Regulations are appended to Petitioner's Petition for Review filed contemporaneously herewith as **Exhibit A**.

INTRODUCTION

1. The court is familiar with the Act and with DOH's previous attempt to promulgate regulations to implement the Act's Chapter 20 research provisions in a manner that unlawfully delegated DOH's authority to private entities and failed to follow the Act's mandate that Chapter 20 requires a meaningful commitment to much-needed research. The Revised Chapter 20 Regulations that are the focus of this case again fail on both counts.

2. By opinion and order entered May 22, 2018 in *AES Compassionate Care, LLC et al. v. Levine*, No. 233 M.D. 233 (Pa. Cmwlth. 2018) (McCullough, J.) (unreported) (*Levine I*), appended to the Petition for Review as **Exhibit B**, this court preliminarily enjoined DOH's first attempt to implement the CR provisions of Chapter 20 of the Act (Original Chapter 20 Regulations), in part because (a) those Original Chapter 20 Regulations unlawfully delegated to ACRCs the vetting and selection of the most qualified entities to be CRs, *see Levine I*, Exhibit B to the Petition for Review at 38-40; and (b) those Original Chapter 20 Regulations required "only a minimal commitment to research to obtain and retain a permit" *see Levine I*, Exhibit B to the Petition for Review at 33-34, notwithstanding the legislature's "intent to implement a robust research program" for medical marijuana. *Levine I*, Exhibit B to the Petition for Review at 49. The Court in *Levine I* also based its grant of a preliminary injunction on its conclusion that whereas Chapter 20 of the Act

prohibited CRs from engaging in “commercial distribution” of medical marijuana in competition with petitioners AES *et al.* and other commercial medical marijuana permittees that hold permits issued under Chapter 6 of the Act, DOH’s Original Chapter 20 Regulations permitted CRs to sell medical marijuana in competition with Chapter 6 permittees. *Levine I*, Exhibit B to the Petition for Review at 34, 49.

3. On June 22, 2018 the General Assembly amended Chapter 20 of the Act to provide, *inter alia*, that CRs are *not* prohibited from engaging in “commercial distribution” of medical marijuana in competition with Petitioner’s members and other Chapter 6 permittees. 35 P.S § 10231.2002(b)(8)-(10). A copy of Act 43 of 2018 amending Chapter 20 of the Act is appended to the Petition for Review as **Exhibit C**. On July 28, 2018, DOH rescinded its Original Chapter 20 Regulations that were the subject of the preliminary injunction in *Levine I*, and thereafter promulgated its Revised Chapter 20 Regulations that are the subject of the Petition for Review.

4. Although Act 43 of 2018 “cured” the error in DOH’s Original Chapter 20 Regulations that permitted CRs, in addition to performing research with ACRCs, to sell medical marijuana in competition with Chapter 6 permittees (by expressly permitting CRs to engage in such commercial competition), Act 43 made no changes that “cured” either (a) the delegation problem or (b) the “minimal commitment to

research” problem because of which the Court in *Levine I* preliminarily enjoined the Original Chapter 20 Regulations.

5. As described in more detail below and in Petitioner’s contemporaneously filed Petition for Review, the Revised Chapter 20 Regulations continue to suffer from (a) the identical delegation problem and (b) the identical “minimal commitment to research” problem that were bases for *Levine I*’s preliminary injunction halting implementation of the Original Chapter 20 Regulations relating to CRs. Accordingly, Petitioner asks that DOH’s Revised Chapter 20 Regulations relating to CRs be preliminarily enjoined.

6. A preliminary injunction is appropriate because:

- a. Petitioner has a clear right to relief, in that the Revised Chapter 20 Regulations continue to (a) unconstitutionally delegate DOH’s responsibility to vet and approve Clinical Registrants (CRs) to private Academic Clinical Research Centers (ACRCs) and (b) ignore the legislature’s intent in Chapter 20 to promote “high quality research.” 35 P.S. § 10231.102(3)(iii), by watering down the commitment to research required of CRs;
- b. Petitioner’s members will be irreparably harmed if the process for choosing CRs to work with ACRCs goes forward now as prescribed in the Revised Chapter 20 Regulations;

- c. the balancing of potential harms to Petitioner and its members versus the respective interested parties in the medical marijuana industry and the public weighs heavily in favor of halting the roll-out of CR/ACRC licensing that the Revised Chapter 20 Regulations initiate until the legal challenge to the Revised Chapter 20 Regulations is resolved; and
- d. a preliminary injunction is suitable relief that will restore the status quo.

See SEIU Healthcare Pennsylvania v. Com., 104 A.3d 495, 501-02 (Pa. 2014) (reciting multi-factor preliminary injunction standard).

7. The court should require only a nominal bond to secure the preliminary injunction as no entity has yet been approved as a CR and any efforts made to date on behalf of aspiring CRs would be required regardless of whether Petitioner had filed this lawsuit; consequently, no entity will sustain reasonably foreseeable damages as a result of the issuance of a preliminary injunction.

8. In addition, Petitioner requests that the court specify in its order granting a preliminary injunction that no appeal from the order will act as an automatic supersedeas under Pa. R.A.P. 1736(b).

FACTS

9. To advance the Act's commitment to "high quality research" in medical marijuana, 35 P.S. § 10231.102(3)(iii), Chapter 20 of the Act authorizes Pennsylvania's eight accredited medical school/teaching hospitals to form ACRCs, which are research clinics. 35 P.S. § 10231. 2002. An ACRC then partners with an entity that needs a medical marijuana grower/processor permit and a dispensary permit to secure status as a CR to supply medical marijuana for use in ACRC-supervised clinical trials and other research. 35 P.S. § 10231. 2003.

10. Both ACRCs and CRs are required to secure DOH approval. Chapter 20 of the Act, as amended by Act 43, provides for an ACRC to contract with a CR to "provide advice" to the CR regarding patient safety and to gain access to medical marijuana for research and clinical trials conducted jointly by the ACRC and the CR. 35 P.S. §§ 10231.2001-2004.

11. Section 2001 expressly provides that a CR is an entity that (a) "is approved by [DOH] to hold a permit as both a grower/processor and a dispensary", (b) "has a contractual relationship" with an ACRC, and (c) is approved by DOH as a CR.

12. Section 2002 authorizes a CR to: (i) "provide medical marijuana at not more than six separate locations"; (ii) sell its medical marijuana products to the CR's dispensaries; (iii) sell or exchange its seeds, plants, or products with Chapter 6

grower/processors; (iv) petition DOH to sell its medical marijuana products to Chapter 6 dispensaries upon a showing that the products “have a practical effect on patients which changes a recommendation within the medical field”; and (v) dispense medical marijuana products to any authorized patient or caregiver possessing a valid medical marijuana card.

13. Chapter 20, as amended by Act 43, does not require that DOH delegate the responsibility of selecting CRs to the ACRCs, but that is the result achieved through DOH’s Revised Chapter 20 Regulations.² That is because the sequence and timing of ACRC and CR applications as prescribed in the regulations, and as administered by DOH, requires each ACRC to select the single entity that may lawfully apply to be that ACRC’s CR, and thus effectively excludes Petitioner’s members from consideration, and preordains the issuance of grower/processor and dispensary permits to the lone CR applicant chosen by the ACRC (several of whom were unsuccessful in their attempts to secure permits through DOH’s normal highly competitive process), by narrowing to a single applicant the “pool” of potential CRs for each ACRC.

14. Chapter 20, as amended by Act 43, does not require DOH to water down the Act’s command that DOH promote “high quality research,” 35 P.S. §

² To the extent they are required by the Act, however, the Act likewise provides for an unlawful delegation of government responsibility to a private entity.

10231.102(3)(iii), but that is the result achieved through DOH's Revised Chapter 20 Regulations, because they tolerate a commitment by CRs to only a minimal involvement in research.

15. DOH's Revised Chapter 20 Regulations thus lack fidelity to the Act in two critical ways, each of which the court in *Levine I* found fatal, and neither of which DOH corrected in revising its Original Chapter 20 Regulations and issuing its Revised Chapter 20 Regulations: (a) they unlawfully delegate DOH's duty to vet and select the eight CRs to the 8 ACRCs; and (b) they abdicate DOH's responsibility to create an ACRC/CR program that demands "high quality research." 35 P.S. § 10231.102 (3) (iii).

Unlawful delegation

16. The application deadline for approval as an ACRC under DOH's Revised Chapter 20 Regulations was September 20, 2018. 48 Pa. B. 5423 (August 25, 2018). All eight of Pennsylvania's accredited medical school/teaching hospitals submitted applications, and all were approved and certified as eligible to enter into a contract with a CR the next day, on September 21, 2018. <https://www.media.pa.gov/Pages/Health-Details.aspx?newsid=532>. See 48 Pa. B. 6629 (October 13, 2018).³

³ The approved ACRCs are: Perelman School of Medicine at the University of Pennsylvania (Penn); Sidney Kimmel Medical College at Thomas Jefferson University (Jefferson); University of Pittsburgh School of Medicine (UPMC); Penn

17. Although Act 43 prohibits an ACRC from contracting with a CR until the ACRC is approved and certified by DOH, 35 P.S. § 10231.2001.1, DOH's Revised Chapter 20 Regulations *required* each ACRC to identify its pre-selected *intended CR* in its ACRC application. 28 Pa. Code § 1211.25(c)(3).

18. The Act provides that DOH may approve up to 8 CRs. 35 P.S. § 10231.2002(a). The application deadline for approval as a CR under DOH's Revised Chapter 20 Regulations was November 8, 2018. 48 Pa. B. 5423 (August 25, 2018).

19. DOH's Revised Chapter 20 Regulations require that a CR applicant include with its application, as a precondition to being considered for CR status, an executed contract with the ACRC with which it has agreed to partner. 28 Pa. Code § 1211.27(b)(7)(i).

20. By requiring a CR applicant to demonstrate that it already has a contract with an ACRC as a prerequisite to filing a CR application, 28 Pa. Code § 1211.27(b)(2) and (b)(7)(i), DOH's Revised Chapter 20 Regulations once again, as under the Original Chapter 20 Regulations this court enjoined, improperly allow each ACRC to select the single entity that may lawfully apply to be that ACRC's CR, and thus effectively preordain the issuance of grower/processor and dispensary

State College of Medicine (Penn State); Lake Erie College of Osteopathic Medicine (LECOM); Lewis Katz School of Medicine at Temple University (Temple); , Drexel University College of Medicine (Drexel); and The Philadelphia College of Osteopathic Medicine (PCOM). 48 Pa. B. 6629 (October 13, 2018).

permits to the CR applicant chosen by the ACRC, leaving DOH with the *fait accompli* of approving the ACRC's choice and issuing a grower/processor permit and a dispensary permit to the single prospective CR privately pre-selected by the ACRC, or denying the CR's application. As the court in *Levine I* held on identical facts, this "creates the appearance that the Department has delegated its duty to regulate the medical marijuana program" to the ACRCs. Exhibit B to the Petition for Review at 39-40.

21. Indeed, it is DOH's duty to vet permit applications and select the most qualified recipients of grower/processor and dispensary permits. DOH's Revised Chapter 20 Regulations thus turn the agency's CR process into an after the fact rubber stamp, which most assuredly is not the permit issuing process envisioned by the General Assembly in Chapter 20 of the Act.

22. This insertion of the ACRC into the CR approval process creates an acknowledged "pay to play" concern that DOH's Revised Chapter 20 Regulations vainly attempt to inoculate against through a prohibition on the ACRC's receipt of kickbacks from the CR or its affiliates, and the requirement of affidavits from each detailing the amounts paid. The pay to play "prohibition," however, is but a "Potemkin Village," where the regulations permit the ACRC, upon "discovery" of a "pay to play" scheme, to simply refund the CR's unlawful payment, allegedly curing the violation. 28 Pa. Code §§ 1211.34 (prohibition); 1211.27(b)(4) (CR affidavit

requirement); 1211.25(c)(3) (ACRC affidavit requirement); 1211.30(c) (ACRC refund).

23. The experience of Petitioner's members is that ACRCs have done very little to assure the selection of the most qualified CR partners, have not contacted Petitioner's members to give them the opportunity to become CR partners, and that only two ACRCs even attempted to use some type of limited RFP process to identify CR candidates. The abandonment of normal RFP processes by the universities and hospitals supports the inference, if not a conclusion, that pay for play is a reality.

24. On information and belief, many if not all the CR applicants had agreements in principle with the medical school/teaching hospital that ultimately chose them to be that ACRC's CR as early as late 2016 or early 2017, long before DOH even reviewed applications or awarded Chapter 6 permits to the 25 best grower/processors and the 50 best dispensaries from many hundreds of applicants.

25. The concern that DOH's process fails to produce the best-qualified CRs is not speculation. On information and belief, several ACRCs have already contracted with several would-be CRs that were losers in DOH's highly competitive application process for grower/processor and dispensary permits:

- a. Curaleaf, successor in interest to Palliatech, an unsuccessful medical marijuana grower/processor permit applicant in DOH's

Phase I that placed 105th out of 177 applications, has been selected by Penn as that ACRC's CR;

- b. MLH Explorations, Inc., Jefferson's chosen CR, applied for a grower/processor permit in Phase II and was denied, placing 26th out of 71 scored applications;⁴
- c. Columbia Care Pennsylvania LLC, UPMC's chosen CR, applied for a grower/processor permit in Phase I and was denied; and
- d. Elemental Health Group, LLC, Penn State's chosen CR, applied for a grower/processor permit in Phase I and likewise was denied.

26. Curaleaf's circumstances offer a window into the core problem with DOH's unlawful delegation to ACRCs and the "rubber stamp" effect of allowing only a single CR applicant per ACRC to compete for that status. In a Canadian Securities Exchange Listing Statement issued October 26, 2018, Curaleaf's parent company, Curaleaf Holdings, Inc., understandably provided potential investors with a rosy description of its Pennsylvania prospects, explaining that "[t]hough it is not currently licensed" in Pennsylvania, it "has partnered with an accredited medical school" to obtain a clinical registrant license, that "[o]nly a private operator that has

⁴ MLH sought to intervene in *Levine I* based on its self-proclaimed status as a "prospective" CR.

entered into a research contract with certain in-state medical schools is eligible to receive a clinical registrant license,” that licenses are expected to be issued in the Fall of 2018, and that Curaleaf “anticipates that it will be operational in Pennsylvania in Q1 2019.” See Curaleaf Holdings, Inc. CSE Form 2A Listing Statement dated October 26, 2018 at 120, attached to the Petition for Review as Exhibit F. For the convenience of the court, page 120 of Curaleaf’s filing is attached hereto as **Exhibit 1**.

27. Curaleaf’s investor disclosure is, unfortunately, appropriately confident, because there is every reason to believe that under the “no competition” CR licensing paradigm DOH has established that has no basis in the statute, DOH will award Curaleaf the grower processor permit it had no chance of winning on a competitive basis in Phase I, the special dispensary permit that allows “up to six dispensaries (as opposed to three under the regular licenses”) *id.*, and CR status, simply because Curaleaf already has a relationship with a prestigious medical school/hospital and thus will be the lone applicant for its position.

28. The insertion of the ACRC into the CR approval process, the “pay to play” concerns it raises that a CR applicant is able to secure DOH approval based on kickbacks to the ACRC instead of the merit of its ability to operate a medical marijuana grower/processor and dispensary dedicated to clinical research, and the resulting unlawful delegation to a private entity of DOH’s responsibility to issue

grower/processor and dispensary permits to the best candidates, are phenomena created entirely by DOH's Revised Chapter 20 Regulations, are not required by, and indeed are inconsistent with the Act.

29. DOH's Revised Chapter 20 Regulations thus result in:

- a. A violation of Article 2, Section 1 of the Pennsylvania Constitution;
- b. The inability of potential CRs other than the entity the ACRC secretly anointed to even apply to DOH for CR status;
- c. The absence from the CR permit issuance process of any semblance of the competitive process that characterized the Phase I and II application processes for the 50 dispensary permits and 25 grower/processor permits authorized under Chapter 6 of the Act;
- d. The fact that ACRCs have already entered contractual relationships with entities that applied for Chapter 6 permits in Phases I and II and were denied;
- e. The likelihood that the most highly qualified grower/processor and dispensary permit candidates will not be involved in Chapter 20 research, thereby frustrating the legislature's desire to

promote “high quality research into the effectiveness and utility of medical marijuana,” Section 102 (3)(iii); and,

- f. DOH’s well-founded concern, as evidenced by its regulations designed to uncover kickbacks paid to ACRCs by prospective CRs and to prohibit them, that factors other than a prospective CR’s merit will influence an ACRC’s choice of CR.

Chapter 20 research goals stymied

30. DOH’s deviation from Chapter 20’s research goals in its Revised Chapter 20 Regulations will bestow super-permits on CRs in exchange for what need only be little or minimal contribution to much-needed research.

31. To obtain CR status, the Revised Chapter 20 Regulations require that, with respect to the essential objective of furthering research studies, a CR applicant provide nothing more than a “description of the research projects the applicant and the certified ACRC **intend** to conduct.” 28 Pa. Code § 1211.27(b)(7)(ii) (emphasis added).

32. To retain CR status, the Revised Chapter 20 Regulations require only similar promises of intent with respect to the essential objective of furthering research: DOH “will not renew an approval” if it determines that “none of the dispensary locations” [i.e., not a single one of the 6 permitted] “are participating in an approved research project,” *and* the CR “does not intend to commence any

additional approved research projects within the first six months following the approval of its application for renewal.” 28 Pa. Code § 1211.31(c).

33. Stated differently, the Revised Chapter 20 Regulations require the CRs to dedicate only 8 percent of their business efforts to research.

PETITIONER’S CLEAR RIGHT TO RELIEF

34. The Revised Chapter 20 Regulations create a CR selection process that violates the Pennsylvania Constitution. By making the “has a contractual relationship with an ACRC” requirement a pre-requisite for a CR application, DOH has delegated its governmental duty to vet and approve medical marijuana grower/processor and dispensary applicants for permits, in violation of Article 2, Section 1 of the Pennsylvania Constitution. The Act provides for up to eight CRs. 35 P.S § 10231.2002. Under the Revised Chapter 20 Regulations, the primary criterion for CR status is that the CR applicant have a contract with an ACRC, and the CR applicant may include only one ACRC in its CR application. 28 Pa. Code § 1211.27(c). The result is that the ACRC determines by privately-negotiated contract the single entity that may apply to be that ACRC’s CR. Instead of exercising its discretion to select the best permittee from a pool of applicants, DOH will be faced with a *fait accompli* – accept the ACRC’s choice or deny the CR’s application. Tellingly, nothing in the Revised Chapter 20 Regulations would permit DOH to reject a CR application based on the conclusion that the CR is not fit to operate a

grower/processor or dispensary facility. 28 Pa. Code § 1211.30 Indeed, the Revised Chapter 20 Regulations' only stated reason for rejecting a CR applicant is failure to comply with DOH's measures vainly designed to combat the justifiable "pay to play" concern – that is, the concern that would-be CRs or their affiliates will circumvent the rigorous application process applicable to all other applicants and buy their way into medical marijuana grower/processor and dispensary permits by making direct or indirect financial payoffs to ACRCs in order to secure the pre-requisite ACRC contract. 28 Pa. Code § 1211.30 (b); *see also* 28 Pa. Code §§ 1211.34 (prohibition); 1211.27(b)(4) (CR affidavit requirement); 1211.25(c)(3) (ACRC affidavit requirement).

35. The Revised Chapter 20 Regulations also fail to track the Act's requirement that CRs engage in meaningful robust research. Instead, the Revised Chapter 20 Regulations, like the Original Chapter 20 Regulations the court enjoined, demand "only a minimal commitment to research to obtain and retain a permit" *see Levine I*, Exhibit B to the Petition for Review at 33-34, notwithstanding the legislature's "intent to implement a robust research program" for medical marijuana. *Levine I*, Exhibit B to the Petition for Review at 49.

PETITIONER'S MEMBERS' IRREPARABLE HARM

36. DOH's Revised Chapter 20 Regulations cause immediate and irreparable harm to Petitioner's members by: (a) eliminating their opportunity to

apply to obtain CR status on a level playing field administered by DOH rather than by ACRCs; (b) allowing would-be CRs already selected by ACRCs but that presently lack the necessary grower/processor and/or dispensary permits (several of whom were denied the permits DOH awarded Petitioner's members because of poor quality proposals) to avoid the searching scrutiny DOH brought to bear in awarding the 25 grower/processor and 50 dispensary permits from among hundreds of applicants; and (c) allowing CRs to obtain and retain CR status by engaging in only a minimal level of research, to the detriment of Petitioner and its members who depend on robust research to maintain and increase the use of medical marijuana by Pennsylvania patients.

37. DOH's Revised Chapter 20 Regulations also cause immediate and irreparable harm to Petitioner and its members because the CR process they initiate, once under way, will not be easily halted, reversed, and unwound after a future ruling on the merits invalidating the Revised Chapter 20 Regulations.

THE BALANCE OF HARMS

38. Petitioner and its members will suffer greater injury if a preliminary injunction is refused than DOH or any other interested party will suffer if it is granted. If DOH moves forward with its CR/ACRC process now, Petitioner and its members will be irreparably harmed. In contrast, if the CR/ACRC process is put on hold pending resolution of the constitutional and important CR/ACRC issues

Petitioner raises, the only effect will be to delay implementation of DOH's watered-down Chapter 20 research program while the court considers whether private ACRCs are constitutionally permitted to select CRs and whether the statute permits the watered-down research requirements in DOH's Revised Chapter 20 Regulations.

39. It is crucial to the stability of Pennsylvania's nascent medical marijuana industry and the public interest that the gulf between Chapter 20's statutory provisions and DOH's Revised Chapter 20 Regulations and the uncertainty thereby created be addressed and resolved before DOH issues CR permits, and CR permittees build out their facilities and commence operations. This balancing weighs heavily in favor of granting a preliminary injunction.

RESTORATION OF STATUS QUO

40. A preliminary injunction will restore all interested parties to the status quo that existed before the Revised Chapter 20 Regulations were issued. DOH's Revised Chapter 20 Regulations were issued on August 18, 2018. CR applications were made available on October 4, 2018 and filed as of November 8, 2018. Petitioner has timely initiated its challenge to the Revised Chapter 20 Regulations and this request to enjoin them before DOH issues CR permits. Issuance of a preliminary injunction now will not prejudice anyone but will instead restore the parties to the status quo that existed before August 18, 2018.

SUITABILITY OF INJUNCTIVE RELIEF

41. A preliminary injunction will abate the harm caused by the Revised Chapter 20 Regulations.

THE PUBLIC INTEREST

42. A preliminary injunction enjoining the Revised Chapter 20 Regulations is in the public interest. The public interest as expressed by the General Assembly is to foster “high quality” research in medical marijuana and its uses. DOH’s Revised Chapter 20 Regulations, as promulgated, will do little to advance that goal. The goal of high quality research that can and should be accomplished by a properly structured formal CR/ACRC program is worth the short wait that will be occasioned by the grant of a preliminary injunction. In the meantime, many of the Petitioner’s members are currently engaging in research.

NOMINAL BOND REQUESTED

43. Petitioner requests that the bond required by Pa. R.C.P. 1531(b) be set at the nominal level of \$100. No entity has yet been approved as a CR and any resources expended by prospective CRs constitute resources that needed to be expended regardless of Petitioner’s lawsuit, such that no entity will sustain reasonably foreseeable damages in the event it is later determined that the requested preliminary injunction was wrongfully issued.

RELIEF FROM AUTOMATIC SUPERSEDEAS

44. Petitioner requests that the court specify in its order granting a preliminary injunction that that no appeal from the order will act as an automatic supersedeas under Pa. R.A.P. 1736(b). The applicable standards for vacating a Rule 1736(b) supersedeas are substantially identical to those for granting a preliminary injunction. *See Department of Environmental Resources v. Jubelirer*, 614 A.2d 199 (Pa. 1989). Accordingly, the Court's grant of a preliminary injunction demonstrates that Petitioner would be entitled to have any Rule 1736(b) supersedeas vacated. Under the circumstances of this case, in the interests of judicial economy, and consistent with the court's action in *Levine I*, Petitioner respectfully requests that the Court make that ruling coincident with its order granting preliminary injunctive relief.

WHEREFORE, Petitioner respectfully requests that the court preliminarily enjoin enforcement of the Revised Chapter 20 Regulations as they relate to CRs, and in particular 28 Pa. Code §§ 1211.27, 1211.28, 1211.30, 1211.31, 1211.32, and 1211.34 as set forth in Petitioner's Petition for Review.

Respectfully submitted,



Kevin J. McKeon, I.D. No. 30428

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*Counsel for Petitioner Medical
Marijuana Advocates for Research*

DATED: November 27, 2018

CERTIFICATE OF COMPLIANCE WITH PUBLIC ACCESS POLICY

I certify that this filing complies with the provisions of the Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts that require filing confidential information and documents differently than non-confidential information and documents.

Respectfully submitted,



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*Counsel for Petitioner Medical
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DATED: November 27, 2018

EXHIBIT 1

PalliaTech holds a producer license and a processing license for adult-use. PalliaTech operates a 20,000 square foot outdoor cultivation center and an adjacent 17,002 square foot indoor facility for large scale CO2 extraction, distillate and formulated products manufacturing. Sales of outdoor flower and pre-rolls commenced in January 2016. Sales of concentrates and oils commenced in April 2017. Sales of indoor flower commenced in June 2017. In July 2017, PalliaTech acquired a dispensary, which launched operations in Portland, Oregon at the end of 2017.

Pennsylvania Operations

Pennsylvania's medical cannabis program was introduced in April 2016 when Governor Tom Wolf signed into law SB 3 "Medical Marijuana Act," which legalized medical cannabis oils for patients with certain qualifying conditions. The law also called for a class of licenses, called "clinical registrant" licenses, whereby accredited medical institutions in the State can partner with medical cannabis companies to conduct research. In mid-June 2017, the Pennsylvania Department of Health ("PADOH") awarded licenses to 12 grower/processors. In late June 2018, the PADOH awarded licenses to 27 different entities to open a total of 52 dispensaries across the State. In February 2018, the first dispensaries opened to patients.

In April 2018, the PADOH approved flower as a permitted medical cannabis product offering, and dispensaries began to offer flower to patients in August 2018. In May 2018, a Commonwealth Court judge halted the Department of Health's planned "clinical registrant" program whereby up to eight Pennsylvania medical schools would partner with licensed medical cannabis organizations to conduct research. In June 2018, Governor Wolf signed a bill to re-implement the clinical registrant program. Regulations for this program are in development. In July 2017, the PADOH licensed 13 additional grower/processors.

There are two primary classes of licenses: licenses to grow and process medical cannabis products, and licenses to dispense medical cannabis products to patients. Grower/processors wholesale products to dispensaries. Originally, only oil-based formulations were permitted, though flower was approved as a product offering in April 2018.

Though it is not currently licensed in Pennsylvania, PalliaTech has partnered with an accredited medical school to obtain a "clinical registrant" license in Pennsylvania. Pennsylvania's medical cannabis program has created this class of license to promote cooperation between industry and academia in the research of medical benefits of cannabis. Under the Medical Marijuana Act and the regulations governing the clinical registrant program, published on August 18, 2018, this license will permit a clinical registrant to operate a cultivation and processing center as well as up to six dispensaries (as opposed to three under the regular licenses). Only a private operator that has entered into a research contract with certain in-state medical schools is eligible to receive a clinical registrant license. The first of such licenses are expected to be issued in the Fall of 2018. The Company anticipates that it will be operational in Pennsylvania in Q1 2019. To support its expected presence in Pennsylvania, the Company has leased a 49,200 square foot production facility in King of Prussia, Pennsylvania.

Additionally, the Company has licensing applications pending in the States of California, Connecticut, Rhode Island, and Virginia

Components of Our Results of Operations

Revenue

Retail and Wholesale Revenue

VERIFICATION

I, Krista Krebs hereby state that I am a principal of Keystone Center of Integrative Wellness, a Phase I medical marijuana dispensary permit holder, and Parea BioSciences, LLC, a Phase II grower/processor permit holder, both of which are members of Medical Marijuana Advocates for Research (MMAR), that I am an officer of MMAR authorized to speak on behalf of MMAR and its members, and that the facts above set forth in the foregoing application for special relief in the nature of a preliminary injunction are true and correct to the best of my knowledge, information and belief. I understand that the statements herein are made subject to the penalties of 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities).



Krista Krebs

VERIFICATION

I, Michael Badey hereby state that I am a principal of Chamounix Ventures, LLC, a Phase I medical marijuana dispensary permit holder, and that I am a member of MMAR authorized to speak on behalf of MMAR and its members, and that the facts above set forth in the foregoing application for special relief in the nature of a preliminary injunction are true and correct to the best of my knowledge, information and belief. I understand that the statements herein are made subject to the penalties of 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities).



Michael Badey

Date: November 27, 2018

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Medical Marijuana Advocates for
Research,

Petitioner,

v.

Rachel L. Levine, MD, Secretary,
Pennsylvania Department of Health,

Respondent.

No. MD 2018


CERTIFICATE OF SERVICE

I hereby certify that I am on this day serving a true and correct copy of the foregoing document upon the persons and in the manner specified below, which service satisfies the requirements of Pa. R.A.P. 121 and Pa. R.A.P. 1514(c):

VIA CERTIFIED MAIL

Hon. Rachel L. Levine
Secretary, Pennsylvania Dept. of Health
Pennsylvania Dept. of Health
Health and Welfare Building
625 Forster Street
Harrisburg, PA 17120

Hon. Josh Shapiro
Pennsylvania Office of Attorney General
Commonwealth of Pennsylvania
16th Floor, Strawberry Square
Harrisburg, PA 17120



Micah R. Bucy

Dated: November 27, 2018